

JUL 10 1996

Smith+Nephew

510(k) Summary of Safety and Effectiveness

Statement

This Summary Of 510(K) Safety And Effectiveness Information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The Assigned 510(K) Number Is :

K961555

This Summary was prepared on: April 18, 1996

Submitter

Smith & Nephew Endoscopy, Inc.
130 Forbes Boulevard
Mansfield, Ma 02048

**Company
Contact**

Amy Walters
Clinical/Regulatory Manager
(508) 339-9700

Device Name

Trade Name: Acufex® TAG and Mini-TAG Bioabsorbable Anchors

Common Name: Suture Anchors

Classification Name: Suture Retention Device - Orthopaedic Use

**Device
description**

The Acufex TAG Bioabsorbable Anchors are wedge-and rod shaped, sterile suture anchors, with a hole through which suture is threaded. the tag anchors are implanted into bone, burying and anchoring the implant and attached suture, which can be used to reattach and secure soft tissue, such as ligaments and tendons.

Three sizes of the devices will be used in the foot, ankle and elbow applications, the Tag 3.7mm Wedge and Rod II and 3.0mm and 2.0mm Wedge Anchors.

465

Intended use

The TAG[®] Bioabsorbable Anchors are intended to be used to secure suture to bone, thereby facilitating the reattachment of soft tissue.

Indications statement

The TAG[®] Bioabsorbable 3.7mm Rod, 3.7mm and 3.0mm Wedge Anchors are indicated for use in soft tissue to bone fixation in the surgical repair of injuries in the foot, ankle and elbow. These additional indications employ the following screw types and sizes:

Size/Style	Indication
3.7mm Rod II	Foot, ankle, elbow
3.7mm Wedge	Foot, ankle, elbow
3.0mm Wedge	Foot, ankle, elbow
3.0mm Wedge Mini-TAG	Foot, ankle
2.0mm Wedge Mini-TAG	Foot, ankle

Substantial Equivalence

The Acufex[®] Mini-TAG and TAG Bioabsorbable Anchors are intended for use as a suture anchor in repairs of soft tissue of the foot, ankle and elbow.

Acufex[®] Mini-TAG and TAG Bioabsorbable Anchors are similar in design, function, and intended use to other devices currently marketed and in commercial distribution, namely Acufex Tag Anchors (Smith & Nephew Endoscopy, Mansfield, MA), and Mitek Mini GII anchors (Mitek Surgical Products, Norwood, MA).

Risks to health have been addressed through the specified materials, processing controls, quality assurance, and compliance to the medical device good manufacturing practices regulations.

The table below summarizes key features of the Bioabsorbable TAG Anchors and the substantially equivalent Mitek Mini GII Anchors and Acufex TAG (non-absorbable) Anchors:

Comparison Chart: Substantially Equivalent Bone Suture Anchors

	Acufex Bioabsorbable TAG Anchors			Acufex TAG Anchors (non-absorbable)		Mitek Anchors
	3.7mm Wedge and Rod	3.0mm Wedge (Mini-TAG and TAG)	Mini-TAG 2.0mm Wedge	3.7mm Wedge and Rod	3.0mm Wedge	Mini-GII
Characteristic Intended Use	facilitate soft tissue to bone reattachment	facilitate soft tissue to bone reattachment	facilitate soft tissue to bone reattachment	facilitate soft tissue to bone reattachment	facilitate soft tissue to bone reattachment	facilitate soft tissue to bone reattachment
Indications for Use	expanded to include foot, ankle and elbow repairs	TAG: expanded to include foot, ankle and elbow repairs Mini-TAG: expanded to include foot and ankle repairs	expanded to include foot and ankle repairs	expanded to include foot, ankle and elbow repairs	expanded to include foot, ankle and elbow repairs	tissue to bone repairs in the foot, ankle and elbow.
Bone Hole Size Diameter	3.7 mm	3.0 mm	2.0mm	3.7 mm	3.0 mm	1.8 mm
Maximum Suture Size (Mono or Braided)	USP #2	USP #1	USP #0	USP #2	USP #1	USP #0
Delivery System	Drill Driver	Drill Driver Delivery Sleeve	Drill Driver Delivery Sleeve	Drill Driver	Drill Driver Delivery Sleeve	Drill Driver
Labeling	Sterile. Single Use Only.	Sterile. Single Use Only.	Sterile. Single Use Only.	Sterile. Single Use Only.	Sterile. Single Use Only.	Sterile. Single Use Only.

**Performance
data**

Extensive performance testing was conducted to ensure the material and design parameters of the TAG Bioabsorbable Anchor are adequate for their intended use and environment: performance testing is described in detail in Section 5 of this submission. Performance testing of the TAG Bioabsorbable Anchors demonstrated the following:


- Pull-out strength of the TAG Bioabsorbable Anchors is equivalent to that of the commercially available TAG Anchors when directly compared in cadaveric bones of the tibia, a worst case model.
- Pull-out strength of the TAG Bioabsorbable Anchors is greater than or equivalent to the "worst-case" clinical loads encountered by the anchors in the specified surgical indications.
- Bridge strength of the TAG Bioabsorbable Anchors is significantly greater than the largest size sutures intended for use with the anchors.
- Pull-out strength of the smallest size sutures intended for use with the TAG Bioabsorbable Anchors is greater than or equivalent to the "worst-case" clinical loads encountered by the anchors in the specified surgical indications
- The "worst-case" clinical loads encountered by the anchors in the specified indications are lower than those encountered in the treatment of shoulder instability, one of the currently cleared indications for use (K946346).


Given the equivalent pull-out strength of the TAG Bioabsorbable Suture Anchors and TAG (non-absorbable) Suture Anchors, the performance testing conducted on the TAG Suture Anchors supports the following conclusions:

- Pull-out strength of the TAG Bioabsorbable Anchors is equivalent to that of the commercially available Mitek Mini-GII Anchors and TAG Anchors. The Mitek Mini-GII Anchors and the TAG Anchors were directly compared in cadaveric bones of the tibia (worst case), foot, ankle, and elbow.
- Repair strengths using the TAG Bioabsorbable Anchors in the foot and ankle are equivalent to standard suture repair techniques for the same soft tissue repairs.

Conclusion

By virtue of their equivalence in design, indications for use, and device performance, the TAG Bioabsorbable Suture Anchors are substantially equivalent to the TAG Suture Anchors and the Mitek Mini-GII Anchors.


Applicant


Date